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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,508	03/23/2004	Stanley M. Crain	96700/879	3407

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary	Application No.	Applicant(s)	
	10/807,508	CRAIN ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-28 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/23/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-28 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment and Information Disclosure Statement filed March 23, 2004 have been received and entered into the application. Accordingly, the specification at page 1 has been amended. Also, as reflected by the attached, completed copies of form PTO/SB/08A&B, the Examiner has considered the cited references.

Specification

The disclosure is objected to because of the following informality:

In the above referenced amendment to the specification, "co-pending" at line 1 should be deleted and at line 2, "allowable" should be deleted and replaced with ---U.S. Patent No. 6,737,400---.

The specification is also objected to as failing to provide proper antecedent basis for the claimed subject matter. In particular, the specification at pages 1-17 fails to include a recitation of the dosage requirements of present claims 9 and 10, i.e., naltrexone dosages of (i) "between about 2 μg/kg body/day weight and about 70 μg/kg body weight/day" (claim 9) and (ii) "between about 4 μg/kg body/day weight and about 45 μg/kg body weight/day" (claim 10). See 37 CFR 1.75(d)(1) and MPEP § 608.01(o) "...applicant may amend the specification to include the claimed subject matter.".

Appropriate correction of the above is required.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 7-10, 13, 19, 22, 23 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (MPEP 2173).

I In claims 7-10, 13, 22, 23 and 26, the term "about" in the expressions "about 0.1 mg/day and about 5 mg/day" (claims 7 and 22), "about 0.3 mg/day and about 3 mg/day" (claims 8 and 23), "about 2 μg/kg body/day weight and about 70 μg/kg body weight/day" (claim 9), "4 μg/kg body/day weight and about 45 μg/kg body weight/day (claim 10) and "about 0.01 mg/day and about 1 mg/day" (claims 13 and 26) is a relative term which renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Because the term "about" would invite, if not require, subjective interpretations of whether or not a particular dosage amount is included by or excluded from the present claims, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims fail to meet either the tenor or express requirements of 35 U.S.C. § 112, second paragraph and are properly rejected.

II In claims 4 and 19, the term "similarly" in the expression "and similarly acting opioid alkaloids or peptides" renders the scope of the claim indefinite because an objective standard for assessing "similarity" has not been provided. Therefore, whether or not a particular opioid alkaloid or peptide was "similar" to a member selected from the group consisting of naltrexone, nalmefene, diprenorphine, naloxone, etorphine, dihydroetorphine and biphalin would be open to subjective interpretation which is not consistent with the requirements of 35 U.S.C. § 112.

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. § 102, a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.,* 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue,* 766 F2d531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile,* 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I Claims 1-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kreek et al. (U.S. Patent No. 4,987,136, cited by the Examiner) who teach pharmaceutical compositions comprising an opioid antagonist such as naloxone, naltrexone or nalmefene (col. 2, lines 58-60) in an dosage amount of "about 2 to about 70 mg/day" (col. 2, line 1). The dosage amount of "about 2" is not distinct from the presently claimed dosage of "between about 0.01 and about 1" (present claims 13 and 26) because "about" can be interpreted as meaning "approximately". Also, for the average 70kg adult, the dosages of present claims 9 and 10 would equate to "between about 0.14 mg/day and about 4.9 mg/day" (claim 9) and "between about 0.28 mg/day and about 3.15 mg/day" (claim 10). The compositions may be in a form suitable for oral, parenteral, buccal, sublingual, transdermal and rectal (i.e., by suppository) administration (col. 5, lines 35-40 and 45-49). Kreek et al. additionally teach that the compositions may be administered to a subject for the purpose of treating irritable bowel syndrome (col. 1, line 18; col. 8, lines 65-68; and Tables 6, 7 and 8 at cols. 11-16).

It is noted that the patentees fail to expressly disclose the functions of the dosage amounts recited in present claims 2, 3, 6, 12, 17, 18, 21 and 25. However, it has been held that "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons

therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). See also MPEP § 2113, last sentence. Here, the Examiner cannot conduct experiments to determine the actual dosage amounts which underlie the functional language employed in the present claims. Therefore, it must be presumed that the actual dosage amounts which correspond to such functional recitations are those set forth in the present specification, i.e., "about 0.1 – about 5 mg/day" for naltrexone (specification at page 10, lines 24-25) and "about 0.01 – about 1 mg/day" for nalmefene (specification at page 10, line 27 – page 11, line 1). These amounts are encompassed by the teachings of the reference for the same ultimate therapeutic purpose of treating irritable bowel syndrome and it therefore must be deemed that such functions are inherent in the method of Kreek et al.

II Claims 16-23, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Crain et al. (U.S. Patent No. 5,585,348 cited by Applicants) who teach pharmaceutical compositions comprising an excitatory opioid receptor antagonist selected from the group consisting of naloxone, naltrexone, diprenorphine, etorphine and dihydroetorphine (col. 4, lines 2-11) in an dosage amount that is 0.1-0.2 mg intravenously for naltrexone (col. 4, line 14) and from 25-50 mg orally for naltrexone (col. 4, lines 14-15). The compositions may additionally be in a form suitable for sublingual, intramuscular, intradermal, subcutaneous, intraperitoneal, intravenous or inhalation administration (col. 6, line 66 – col. 7, line 2).

The recitation in the present claims that the composition is intended for a use not disclosed in Crain et al. is noted, but is not a patentable distinction because such recitation does not impart any physical or otherwise material feature to the composition that is not present in the composition of Crain et al.

Double Patenting

Statutory

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-15 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of prior U.S. Patent No. 6,194,382 (cited by Applicants). This is a double patenting rejection.

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over (i) claims 1-12 of U.S. Patent No. 6,395,705 (cited by

Applicants) or (ii) claims 1-12 of U.S. Patent No. 6,737,400 (cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because in both the '705 and '400 patents, claim 1 is a combination of present claims 1 and 3. Therefore, the patented claims anticipate the present claims.

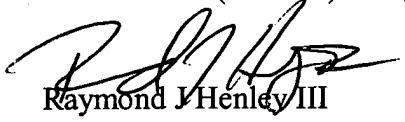
The references cited on the attached form PTO-892 and not relied on by the Examiner have been included to show the general state of the art.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J Henley III
Primary Examiner
Art Unit 1614

February 27, 2005